REMARKS

Claims 1-8, 11-17 and 20-27 are pending in this application. No claim amendments are made herein. Thus, no new issues are raised. Applicants respectfully submit arguments for consideration, and request reconsideration of the pending claims in light of the arguments herein.

Information Disclosure Statement - Form 1449

Applicants note that the Office Action Summary indicates that "Information Disclosure Statement(s) (PTO-1449) Paper No(s) 01/25/02" was attached to the Office Action. However, a Form PTO-1449 was not attached to Applicants' copy of the Office Action. Applicants request that the Office provide an Examiner-initialed copy of the January 25, 2002 Information Disclosure Statement (Form PTO-1449) with the next written communication from the Office.

Restriction Requirement

Applicants acknowledge that the restriction requirement has been made final.

Rejections Withdrawn

Applicants note that the Examiner has withdrawn all of the objections to the specification and all of the rejections of the claims set forth in the previous Office action, mailed August 21, 2003.

Telephone Interview

Applicants thank Examiners Ford and Minnifield for the courtesy of a telephone interview with their representatives, Tanya Harding and Debra Gordon, on May 27, 2004. During the telephone conference, the rejections under 35 U.S.C. §102(b) and the corresponding references (Norgard *et al., J. Clin. Microbiol.,* 20(4):711-717, 1984; and Hunter *et al., J. Clin. Microbiol.*, 16(3):483-486, 1982) were discussed. It was acknowledged by all participants that each of the pending anticipation rejections under §102(b) is based solely on inherency. The single 35 U.S.C. §103(a) rejection citing Hunter *et al., J. Clin. Microbiol.*, 16(3):483-486, 1982 ("Hunter") was also briefly discussed.

As an initial matter, Examiner Minnifield stated that the §102(b) rejection of 1-2, 5-6, 11-15 and 30 based on Norgard *et al., J. Clin. Microbiol.,* 20(4):711-717, 1984 ("Norgard")

would be withdrawn because Norgard recites isolated antibodies, which the Office acknowledged are relevant only to claims 16 and 31. The Examiners also agreed that the §103(a) rejection citing Hunter would be overcome if the §102(b) rejection citing Hunter was overcome.

Applicants' representatives pointed out MPEP §2112, which states (i) "[t]he fact that a certain result or characteristic may occur or be present is not sufficient to establish the inherency of that result or characteristic" (emphasis in original), and (ii) that an "examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art" (emphasis in original).

Applicants' representatives explained that the isolated acidic repeat polypeptides recited in the claims could not and did not necessarily flow from the references cited in the Office action. Discussion ensued regarding (i) the term "isolated," (ii) the characteristics of the crude desoxycholate *T. pallidum* preparation of Hunter, and (iii) the Portnoy and Magnuson article (*J. Immunol.*, 75(5):348-55, 1955), which describes the desoxycholate extraction procedure used in Hunter.

Agreement was not reached on all issues. However, Applicants believe this Response conforms to suggestions offered by the Examiners.

Claim Rejections under 35 U.S.C. §102:

Claims 1-2, 5-6, 11-16 and 30-31 have been rejected under 35 U.S.C. §102(b) allegedly as being inherently anticipated by Norgard *et al.* (*Journal of Clinical Microbiology*, October 1984, p. 711-717) ("Norgard"). Applicants traverse this rejection for the reasons stated below.

Examiner Minnifield stated that this rejection was inappropriate and would be withdrawn with regard to claims 1-2, 5-6, 11-15 and 30. Based on the Examiner's representation, Applicants request that this rejection of claims 1-2, 5-6, 11-15 and 30 be withdrawn.

Claims 16 and 31 are drawn to methods of detecting *T. pallidum* and recite, in relevant part, isolated anti-*T. pallidum* antibodies ". . . specific for an immunogenic peptide of *T. pallidum* acidic repeat protein . . . compris[ing] the amino acid sequence $EVEDX_1PX_2VVEPASX_3X_4EGGER$, wherein X_1 is A or V; X_2 is K or G; X_3 is E or G; and X_4 is R or H . . . ." Norgard does not expressly or inherently teach an antibody with this specificity.

Norgard refers to thirteen monoclonal antibodies (see Table 1 in Norgard) having varying affinities for unidentified *T. pallidum* proteins. *T. pallidum* expresses over 1000 proteins (see, for example, ftp.ncbi.nih.gov/genomes/Bacteria/Treponema_pallidum/NC_000919.ptt). Each of the >1000 *T. pallidum* protein can have numerous antibody binding sites (*i.e.*, epitopes). Thus, the number of possible anti-*T. pallidum* antibodies that could be isolated *vastly* exceed the thirteen monoclonal antibodies described by Norgard.

As discussed above, MPEP §2112 directs that the "examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Thus, in this case, the Office must show that Norgard necessarily teaches methods employing an antibody specific for the immunogenic peptide of *T. pallidum* acidic repeat protein as recited in claims 16 and 31. In light of the many thousands (perhaps more) of possible anti-*T. pallidum* antibodies that can be envisioned, it is **extremely unlikely** that one of the thirteen Norgard antibodies is ". . . specific for an immunogenic peptide of *T. pallidum* acidic repeat protein . . . compris[ing] the amino acid sequence $EVEDX_1PX_2VVEPASX_3X_4EGGER$, wherein X_1 is A or V; X_2 is K or G; X_3 is E or G; and X_4 is R or H . . . ." As a result, the Office has not met its burden to show "the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Moreover, the Office action has provided no basis in fact and/or technical reasoning that would support such a contention. Thus, the elements of claims 16 and 31 are not inherently disclosed in the cited reference.

In light of the foregoing argument, Applicants request that this rejection of claims 16 and 31 be withdrawn.

Claims 1-2, 5-7, 11-16 and 30-31 have been rejected under 35 U.S.C. §102(b) allegedly as being inherently anticipated by Hunter *et al. (Journal of Clinical Microbiology*, September 1982, p. 483-486) ("Hunter"). Applicants traverse this rejection for the reasons stated below.

With regard to claims 16 and 31, Hunter does not expressly or inherently teach **any** isolated antibodies at all, and certainly does not teach isolated antibodies with the specificity of those recited in claims 16 and 31. Because Hunter does not expressly or inherently teach all of the elements of claims 16 and 31, Hunter cannot anticipate these claims. Thus, Applicant request that this rejection of claims 16 and 31 be withdrawn.

With regard to claims 1-2, 5-7, 11-15 and 30:

Hunter describes a sodium desoxycholate extract of *T. pallidum.* The extract is prepared using the procedure of Portnoy and Magnuson, (*J. Immunol.*, 75(5):348-55, 1955) with only minor modifications (see page 483, column 2, "SD extraction" in Hunter). A copy of the Portnoy and Magnuson article is attached hereto.

As previously discussed, MPEP §2112 requires that the Office "provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Thus, for this rejection, the Office must show that Hunter necessarily teaches methods of detecting *T. pallidum* or anti-treponemal antibodies using the specific *T. pallidum* polypeptides recited in claims 1-2, 5-7, 11-15 and 30. In relevant part, claim 1 (and its dependent claims) recites "isolated *Treponema pallidum* acidic repeat protein or one or more isolated, immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein . . , wherein the acidic repeat protein or the isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein comprises the amino acid sequence $EVEDX_1PX_2VVEPASX_3X_4EGGER$, wherein X_1 is A or V; X_2 is K or G; X_3 is E or G; and X_4 is R or H."

Neither Hunter nor Portnoy and Magnuson identify the proteins or other components contained in the sodium desoxycholate extract. In fact, Portnoy and Magnuson expressly state that "limited information available does not permit chemical characterization of the [desoxycholate extract]" (see page 352, column 2 in Portnoy and Magnuson). Thus, even the

references cited by the Office admit that the desoxycholate extract of *T. pallidum* described by Hunter (and Portnoy and Magnuson) contains an **unknown mixture of some fraction of *T. pallidum* proteins** (and possibly other cellular components). By definition, one cannot know that a specific protein having a particular amino acid sequence (as recited in claim 1 and its dependent claims) is necessarily contained within an unknown mixture of some fraction of *T. pallidum* proteins. Thus, the Office has not met its burden to show "the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Moreover, the Office action has provided no basis in fact and/or technical reasoning that would support such a contention.

Based only on the foregoing argument, this rejection of claims 1-2, 5-7, 11-15 and 30 should be withdrawn.

However, even if a specific acidic repeat protein or peptide could be taught by an unknown mixture of proteins, Federal Circuit case law is clear that an anticipatory reference (even one cited for inherent disclosure) must be enabling (*e.g.*, *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d, 1313 (Fed Cir. 2003)). Thus, a reference cited as anticipatory must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation (MPEP §2164.01). Certainly, the mixed bag of undefined *T. pallidum* proteins (and possibly other cellular components) described by Hunter is not enabling for methods of using the specific isolated acidic repeat proteins or peptides referenced in the claims, because one of ordinary skill in the art could not make and use something s/he did not know existed until after Applicants described it.

Based on all of the foregoing arguments, Applicants request that this rejection be withdrawn.

Claim Rejections under 35 U.S.C. §103(a):

Claim 28 has been rejected under 35 U.S.C. §103(a) allegedly as unpatentable over Hunter. Applicants traverse this rejection for the reasons stated below.

In order to establish a *prima facie* case of obviousness, the Office action must offer references that teach or suggest all of the elements of the rejected claim. Claim 28 recites, in relevant part, ". . . the method of claim 1." As discussed above, Hunter does not teach or suggest all of the elements of amended claim 1. Thus, all the claim limitations of claim 28 are not taught or suggested by the cited reference and a *prima facie* case of obviousness is not established (MPEP §1504.03). The Office action has failed to meet this burden; therefore, this rejection should be withdrawn.

CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If it may further issuance of these claims, the Examiner is invited to call the undersigned at the telephone number listed below.

Respectfully submitted,

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